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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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79990 7590 09/03/2009

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EXAMINER	
WOZNICKI, JACQUELINE	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
09/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,722	LAITENBERGER ET AL.	
	Examiner	Art Unit	
	JACQUELINE WOZNICKI	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 July 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/21/08 and 10/27/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "envelope" mentioned in **claim 8** must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 2-3 are objected to because of the following informalities: Line 2 of **claim 2** and line 1 of **claim 3** recite the implant "further *compromises*..." rather than "further *comprises*...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding **claim 4**, applicant recites a "cancelling remainder" of lobes. It is unclear what a cancelling remainder is and how an area bounded by a set of lobes can equal the area bounded by this.

Regarding **claim 6**, applicant refers to "said axis" in line 2, but there is insufficient antecedent basis for this in the claims.

Regarding **claim 8**, the claim refers to an envelope in line 2, but it is unclear how an envelope fits into this invention.

Claim Rejections - 35 USC § 102

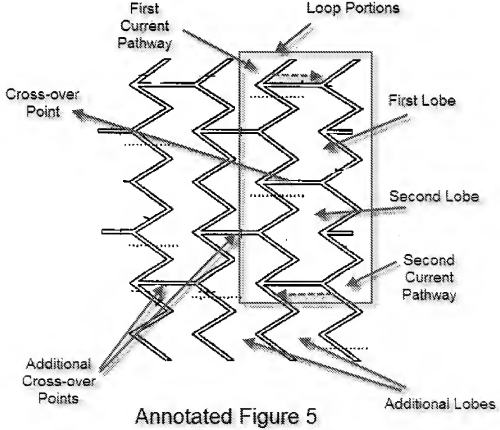
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 11-16, 18-21, 23, 25-29, and 32-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Pacetti (US 6712844 B2).



Annotated Figure 5

Regarding **claim 1**, Pacetti teaches **an implant comprising: electrically-conductive** (Column 6, lines 5-8) **closed loops** (Figure 5, item 42) **forming an apertured wall** (Figure 5) **of the implant with an interior volume** (Abstract, line 1; a stent is a tube, which has an interior volume)**, each of said loops being formed from loop portions** (see Annotated Figure 5, above) **providing electrically- conductive current pathways** (Column 6, lines 5-8) **within which eddy currents are liable to be induced when subjected to a time-dependent external magnetic field** (Column 6, lines 27-29)**, each of said loops including a first current pathway and a second current pathway** (Annotated Figure 5) **wherein said first current pathway and said second current pathway are arranged such that, regardless of the direction of said external magnetic field, the direction of the eddy current that would be induced by said field in said second current pathway is the reverse of the direction of the eddy current that would simultaneously be induced by said field in said first current pathway, thereby to prevent flow of eddy currents in each of said loops** (Annotated Figure 5; the directions of the current flowing will be opposite, due to nonconductive connectors present in the loop portion (Column 7, lines 4-7 and 12-14))**.**

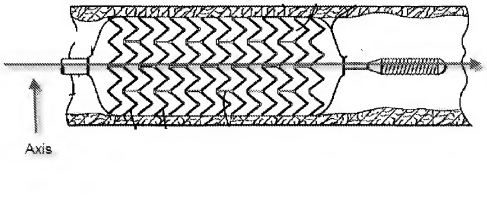
Regarding **claim 2**, Pacetti further teaches each of the loops having loop portions (Annotated Figure 5) formed as a first lobe (Annotated Figure 5) and as a second lobe (Annotated Figure 5) of a figure of eight,

and further comprises a cross-over point (Annotated Figure 5) between said first lobe and said second lobe.

Regarding **claim 3**, Pacetti further teaches an electrically insulating joint (Column 7, lines 4-7 and 12-14) between said two loop portions at the cross-over point (Column 7, lines 2-3; the cross-over point as shown in Annotated Figure 5 is located in a connector).

Regarding **claim 4**, as best understood, Pacetti further teaches each of the loops having additional lobes (Annotated Figure 5) and additional cross-over points between the additional lobes (Annotated Figure 5), with the areas bounded by the lobes being such that, in aggregate, the area bounded by one set of lobes equals the area bounded by a cancelling reminder of the lobes (Figure 2 shows the area represented by the lobes as being symmetrical, and so the area bounded by one will be equal to the another).

Annotated Figure 2



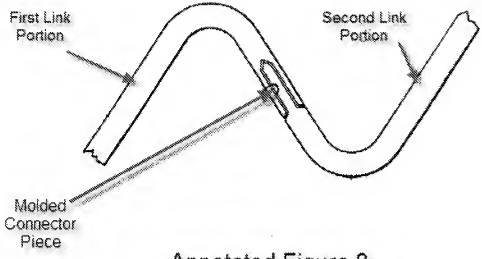
Regarding **claim 5**, Pacetti further teaches the implant having a central longitudinal axis and said interior volume is tubular and centered on said axis (see Annotated Figure 2, above).

Regarding **claim 11**, Pacetti further teaches the loop portions corresponding to struts that are joined end-to-end to each other (Figure 5, item 49) and can deploy in use to form a zigzag portion (Figure 5; Column 5, lines 48-49).

Regarding **claim 12**, Pacetti further teaches the plurality of loops being arranged mutually axially adjacent and spaced along the axis (Figure 2 and Figure 5).

Regarding **claim 13**, Pacetti further teaches adjacent loops being connected to each other by electrically-insulating links (Column7, lines 2-7 and 12-14).

Regarding **claim 14**, Pacetti further teaches each of the loops including a plurality of electrically-insulating links that connect spaced loop portions of said loop (see the rejection to **claim 13** above, and Annotated Figure 5).



Annotated Figure 8

Regarding **claim 15**, Pacetti further teaches each link being a mechanical coupling (Figure 8 and Column8, lines 7-9) with a first cooperating link portion (see Annotated Figure 8, above) and a second cooperating link portion (Annotated Figure 8).

Regarding **claim 16**, Pacetti teaches the cooperating portions being able to move relative to each other (Annotated Figure 8 and Column 8, lines 7-14; the portions will be able to move relative to each other, for example when the stent is being manufactured and the "tongue" portion is placed in the "groove" portion after they have been cut, the two will be "movable" relative to each other).

Regarding **claim 18**, Pacetti further teaches a layer of bonding material between the cooperating link portions (Annotated Figure 5, Column 7, lines 2-13; adhesive is a bonding material).

Regarding **claim 19**, Pacetti further teaches the bonding material being ceramic (Column 7, lines 38-39).

Regarding **claim 20**, Pacetti further teaches the bonding material being an adhesive composition (Column 7, lines 2-3).

Regarding **claim 21**, Pacetti further teaches the mechanical coupling comprising interlocking fingers (Figure 8, item 56 and Column 8, lines 7-9).

Regarding **claim 23**, Pacetti further teaches each link including a molded connector piece (Annotated Figure 8).

Regarding **claim 25**, Pacetti further teaches the wall of the implant being an apertured tube (Figure 2 and Abstract; a stent is an apertured tube).

Regarding **claims 26-27**, Pacetti further teaches the implant being made of nickel-titanium shape memory alloy and stainless steel (Column 6, lines 6-7).

Regarding **claim 28**, Pacetti further teaches the implant being a stent (Abstract).

Regarding **claim 29**, Pacetti further teaches the stent being radially expansible from a radially compact delivery configuration (Column 5, lines 3-7)to a radially larger deployed configuration (Column 5, lines 26-29) and

the stent being capable of being delivered transluminally by a catheter (Figure 1).

Regarding **claim 32**, Pacetti further teaches the implant being a graft (Column 8, lines 31-32).

Regarding **claim 33**, Pacetti further teaches the implant being a self-expanding implant (Column 8, line 36) delivered transluminally in a radially compact configuration (Column 5, lines 3-7) and capable of self-expansion into a radially larger deployed configuration at an implant site (Column 5, lines 26-29).

Regarding **claim 34**, Pacetti further teaches each closed loop exhibiting lobes with an equal lobe area on opposite sides of the interior volume (Annotated Figure 5 and Figure 2).

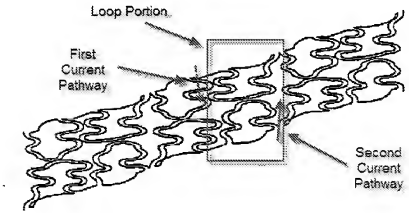
Regarding **claim 35**, Pacetti teaches **an electrical conductor** (Column 6, lines 5-8)**, said electrical conductor having a plurality of closed loops** (Annotated Figure 5 "loop portions") **electrically insulated from each other** (Column 3, lines 55-57 and Column 7, lines 2-3), **each of said closed loops having a periphery of a string of equal area lobes that are within said closed loop** (Figure 2). However, Pacetti fails to teach **every one of said lobes having a counterpart lobe located diametrically opposite on the implant tube**.

Regarding **claim 35** however, it is inherent in the construction of Pacetti's implant that each lobe must have a counterpart lobe located diametrically opposite it on the implant tube. If this was not the case, the

current pathways created with the implant is placed under a magnetic field would not cancel each other out, and the implant would not prevent the Faraday Cage effect.

Regarding **claim 36**, Pacetti further teaches each of the loops having an even number of lobes (Annotated Figure 5; each loop has two lobes).

Claims 1 and 6-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Bucker et al. (WO-03015662 A1; US 20040249440 A1 is being used as a translation thereof).



Annotated Figure 2d

Regarding **claim 1**, Bucker teaches **an implant comprising: electrically-conductive** ([0006]; a metallic material is electrically conductive) **closed loops** (Figures 2a-2e) **forming an apertured wall** (Figure 1) **of the implant with an interior volume** (Figure 1), **each of**

said loops being formed from loop portions (see Annotated Figure 2d, above) **providing electrically- conductive current pathways** ([0006]; a metallic material is electrically conductive) **within which eddy currents are liable to be induced when subjected to a time-dependent external magnetic field** ([0003]), **each of said loops including a first current pathway and a second current pathway** (Annotated Figure 2d) **wherein said first current pathway and said second current pathway are arranged such that, regardless of the direction of said external magnetic field, the direction of the eddy current that would be induced by said field in said second current pathway is the reverse of the direction of the eddy current that would simultaneously be induced by said field in said first current pathway, thereby to prevent flow of eddy currents in each of said loops** ([0017]; because the endoprosthesis does not form a closed circuit, current will not flow).

Regarding **claims 6-7**, as best understood, Bucker further teaches each of the loops wrapping around an axis in the form of a spiral (Figure 4a) with an integral whole number of turns (being at least 3 turns) (Figure 4a; shows 4 turns).

Regarding **claim 8**, as best understood, Bucker further teaches each of the loops lying within an envelope that is transverse to an axis (Figure 4a; the axis is taken to be the longitudinal axis of symmetry down the center of the lumen of the stent).

Regarding **claim 9**, Bucker further teaches each of the loops wrapping about an axis in a path that spirals around the axis from one end of the implant to the other (Figure 4a).

Regarding **claim 10**, Bucker further teaches the pitch of the spiral path being constant (Figure 4a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Raulerson (US 5599311 A).

Regarding **claim 17**, Pacetti fails to teach the cooperating portions being constituted as a hook portion and an eye to receive the hook portion.

However, Raulerson teaches a hook and eye being used to connect two parts of a stent (Column 7, lines 35-41; Raulerson teaches the equivalence of hook and eye (i.e. Velcro) to interlocking pieces as taught by Pacetti). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the implant as taught by Pacetti with the hook and eye connection as taught by Raulerson because a hook and eye connection would allow the strut portions to be removably connectable to each other, but not rigid and immovable, which will increase the flexibility of the stent.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Lenker et al (US 6176875 B1).

Regarding **claim 22**, Pacetti teaches the mechanical coupling comprising mechanically-engaging surfaces (Annotated Figure 8; "molded connector piece"), but fails to fails to teach them being in combination with at least one restraining strap that overlies the engaging surfaces. However, Lenker teaches restraining straps that lay over the engaging surfaces (Figure 5C and Column 9, lines 44- 47) It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the implant as taught by Pacetti with the restraining strap as taught by Lenker because the restraining strap will prevent a self-expanding stent from expanding before a surgeon has delivered the stent to the desired implant position.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Shanley et al. (US 20040122506 A1).

Regarding **claim 24**, Pacetti teach each link including a portion that is locally thinned with respect to the thickness of the wall of the implant. However, Shanley teaches a portion of connecting struts being thinner than the wall of the implant (Figure 1; item 14 is a connecting strut, which has a width that is thinner than the struts that comprise the wall of the impant (such as item 22)). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the implant as taught by Pacetti with thin connectors as taught by Shanley so the least amount of material possible will be implanted into a patients body,

reducing the likelihood of implant rejection and infection from foreign materials.

Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pacetti in view of Tomonto et al. (US 5733326 A)

Regarding **claims 30-31**, Pacetti fails to teach the implant being a filter or a valve. However, Tomonto teaches the implant being a filter or a valve (Column 3, lines 25-28). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the stent implant as taught by Pacetti with the embodiments as a filter or valve as taught by Tomonto because the problem solved by Pacetti (preventing the Faraday cage effect when an implant is placed in a magnetic field) would be equally and logically applicable to other implant devices that a doctor might need to see through while a patient is getting an MRI and is exposed to a magnetic field, such as a valve or a filter.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Hong et al. (US 6805707 B1),Hong et al. (US 6776794 B1), Hong et al. (US 6749629 B1), Hong et al. (US 20040172128 A1), Gray et al. (US 20050049686 A1), Gray et al. (US 20050049688 A1), Wang et al. (US 20040158310 A1), and Martin (US 20060136039 A1).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE WOZNICKI whose telephone number is (571)270-5603. The examiner can normally be reached on M-R, 9 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on (571)272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul Prebilic/
Primary Examiner, Art Unit 3774

/JACQUELINE WOZNICKI/
Examiner, Art Unit 3774
08/27/09